

November 25, 2003

Mr. Has Shah
Manager
The American Chemistry Council
Brominated Biocides Panel DMH task Force
1300 Wilson Boulevard
Arlington, VA 22209

Dear Mr. Shah:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 5,5-Dimethylhydantoin posted on the ChemRTK HPV Challenge Program Web site on August 1, 2003. I commend The American Chemistry Council Brominated Biocides Panel DMH Task Force for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Panel advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:
5,5-Dimethylhydantoin (DMH)**

Summary of EPA Comments

The American Chemistry Council (ACC) Brominated Biocides Panel submitted a test plan and robust summaries to EPA for 5,5-dimethylhydantoin dated July 10, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on August 1, 2003.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The submitter needs to provide the reference for the experimental melting point value of 178 °C or provide a measured value for melting point following OECD guidelines or from a reliable literature source. The submitter also needs to provide measured vapor pressure and water solubility data either following OECD guidelines or from a reliable literature source.
2. Environmental Fate. The submitter needs to recalculate the fugacity endpoint using measured physicochemical data.
3. Health Effects. All appropriate SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program.
4. Ecological Effects. Available data are adequate for fish and invertebrate endpoints for the purposes of the HPV Challenge Program. The submitter needs to provide adequate data for the algal endpoint.

EPA requests that the submitter advise the Agency within 60 days of any modification to its submission.

EPA Comments on the 5,5-Dimethylhydantoin (DMH) Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

Available boiling point and partition coefficient values are acceptable for the purposes of the HPV Challenge Program.

Melting point. The submitter needs to provide the reference for the experimental melting point value of 178 °C. If this is not possible, the submitter needs to provide a measured value for melting point following OECD guidelines or from a reliable literature source. A melting point estimated with MPBWIN is not sufficient for the purposes of the HPV Challenge Program unless below 0 °C.

Vapor pressure. The submitter presented an estimated value of 1.36×10^{-6} mm Hg at 25 °C. Estimated vapor pressure values above 7.5×10^{-8} mm Hg (1×10^{-5} Pa) are not adequate for the purposes of the HPV Challenge Program. The submitter needs to provide measured vapor pressure data, either following OECD guidelines, or from a reliable literature source.

Water solubility. The submitter presented a qualitative assessment of “soluble” and a calculated value of 4516 mg/L using WSKOW v. 1.40. Qualitative and estimated water solubility values are not adequate for the purposes of the HPV Challenge Program. The submitter needs to provide measured water solubility data either following OECD guidelines or from a reliable literature source.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data provided by the submitter for photodegradation, stability in water, and biodegradation are adequate for the purposes of the HPV Challenge Program.

Fugacity. The submitter needs to recalculate the fugacity results using measured physicochemical data. Running the model using only estimated data is not adequate for the purposes of the HPV Challenge Program. The use of estimated or calculated values introduces uncertainties that then become magnified in modeling applications. Data from published sources are acceptable, as long as the submitter identifies the sources.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Many of the studies did not report the purity of the test substance. However, most of the endpoints had one critical study in which the purity of the substance was reported. For the genotoxicity studies, most studies did not report the purity of the test substance. In addition, some of the genotoxicity studies did not test concentrations up to the limit doses suggested by the OECD guidance documents. However, given the number of genotoxicity studies available as well as the results of carcinogenicity tests, the weight of the evidence suggests there is no need for additional genotoxicity testing.

Ecological Effects (fish, invertebrates, and algae)

EPA disagrees with the submitter's rationale, based on the predicted and measured low toxicity values for fish and invertebrates, for not conducting an algal test. EPA suggests the submitter provide SAR and data on an analog to show that the algal endpoint value would be similar to those reported for fish and invertebrates. The SAR information needs to be reported in robust summary format.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.